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Longhorn Vaccines and Diagnostics, LLC*

**IN THE UNITED STATES DISTRICT COURT
DISTRICT OF UTAH, CENTRAL DIVISION**

LONGHORN VACCINES &
DIAGNOSTICS, LLC., a Delaware limited
liability company,

Plaintiff,

v.

SPECTRUM SOLUTIONS LLC, a Utah
limited liability company;

Defendant.

Case No. 2:20-cv-00827

District Judge David Barlow

AMENDED COMPLAINT

JURY DEMAND

Plaintiff Longhorn Vaccines & Diagnostics, LLC. (“Longhorn”) hereby alleges and complains against Defendant Spectrum Solutions, LLC (“Spectrum”) as follows:

THE PARTIES, JURISDICTION, AND VENUE

1. Plaintiff Longhorn is a Delaware limited liability company registered to do business in Maryland and with its headquarters located in Bethesda, Maryland.
2. Defendant Spectrum is a Utah limited liability company with its headquarters in West Jordan, Utah.

3. This Court has exclusive original subject matter jurisdiction pursuant to 28 U.S.C. § 1331 and 1338(a).

4. This Court has general and specific personal jurisdiction over Spectrum because, *inter alia*, Spectrum is domiciled in the State of Utah, Spectrum and/or its agents regularly do business in the State of Utah and in this District, and Spectrum and/or its agents infringe the patents described below in this State and District, deriving revenue and value therefrom, so as to purposefully avail itself of the privilege of conducting business within this State and District.

5. This Court may exercise jurisdiction over Spectrum on the ground that, *inter alia*, the conduct of Spectrum and/or its agents as alleged herein caused and continues to cause injury to Longhorn in the State of Utah and in this District

6. Venue is proper under 28 U.S.C. § 1391(b) and (c) and 1400(b) because Spectrum has a regular and established place of business in this District and is distributing and selling the infringing product in this District.

LONGHORN'S ASSERTED PATENTS

7. Longhorn develops, manufactures, and sells chemicals and solutions used to collect and preserve biological samples for testing.

8. Longhorn's chemicals and solutions are protected by certain of its valid and enforceable United States Patents.

9. On December 27, 2011, United States Patent No. 8,084,443 ("the '443 Patent"), entitled "Biological Specimen Collection and Transport System and Method of Use," was assigned by all inventors to Longhorn and duly and legally issued by the United States Patent and Trademark Office. To date, all maintenance fees have been paid and the '443 Patent is a

valid and enforceable United States patent. A true and correct copy of the '443 Patent is attached as Exhibit A to this Complaint.

10. On October 23, 2012, United States Patent No. 8,293,467 (“the ’467 Patent”), entitled “Biological Specimen Collection and Transport System and Method of Use,” was assigned by all inventors to Longhorn and duly and legally issued by the United States Patent and Trademark Office. To date, all maintenance fees have been paid and the ’467 Patent is a valid and enforceable United States patent. A true and correct copy of the ’467 Patent is attached as Exhibit B to this Complaint.

11. On April 9, 2013, United States Patent No. 8,415,330 (“the ’330 Patent”), entitled “Biological Specimen Collection and Transport System and Method of Use,” was assigned by all inventors to Longhorn and duly and legally issued by the United States Patent and Trademark Office. To date, all maintenance fees have been paid and the ’330 Patent is a valid and enforceable United States patent. A true and correct copy of the ’330 Patent is attached as Exhibit C to this Complaint.

12. On March 11, 2014, United States Patent No. 8,669,240 (“the ’240 Patent”), entitled “Biological Specimen Collection and Transport System and Method of Use,” was assigned by all inventors to Longhorn and duly and legally issued by the United States Patent and Trademark Office. To date, all maintenance fees have been paid and the ’240 Patent is a valid and enforceable United States patent. A true and correct copy of the ’240 Patent is attached as Exhibit D to this Complaint.

13. On December 15, 2015, United States Patent No. 9,212,399 (“the ’399 Patent”), entitled “Biological Specimen Collection and Transport System and Method of Use,” was

assigned by all inventors to Longhorn and duly and legally issued by the United States Patent and Trademark Office. To date, all maintenance fees have been paid and the '399 Patent is a valid and enforceable United States patent. A true and correct copy of the '399 Patent is attached as Exhibit E to this Complaint.

14. On June 20, 2017, United States Patent No. 9,683,256 (“the '256 Patent”), entitled “Biological Specimen Collection and Transport System and Method of Use,” was assigned by all inventors to Longhorn and duly and legally issued by the United States Patent and Trademark Office. To date, all maintenance fees have been paid and the '256 Patent is a valid and enforceable United States patent. A true and correct copy of the '256 Patent is attached as Exhibit F to this Complaint.

15. Longhorn owns all rights, title, and interest in each of the '443 Patent, the '467 Patent, the '330 Patent, the '240 Patent, the '399 Patent, and the '256 Patent (together, the “Asserted Patents”) by assignment from the named inventors recorded by the USPTO assignment branch at Reel/Frame 021620/0838.

16. Following the issuance of each of the Asserted Patents, Longhorn has properly marked its products with the Asserted Patents.

LONGHORN'S PATENTED TECHNOLOGY

17. It is common knowledge to one skilled in the art that an aqueous composition that comprises a) one or more chaotropes; b) one or more detergents and/or surfactants; c) one or more reducing agents; d) one or more chelators; and e) one or more buffers serves the purpose of denaturing proteins, inactivating nucleases, killing pathogens, and not degrading nucleic acid of a sample suspected of containing pathogens when the sample is contacted with the composition.

18. Longhorn's patents are directed to chemical compositions that preserve biological samples and methods of using the compositions to collect and preserve said biological samples to test for pathogens.

19. Longhorn's inventions provide clinical/environmental collection solutions and methods that efficiently achieve at least three, and preferably all four of the following: 1) kill or inactivate potentially-infectious pathogens, so that they are non-viable and can be safely handled, shipped or transported; 2) lyse cells to release RNAs and/or DNAs from the biological specimen contained in the collection system; 3) protect the released or 'naked' polynucleotides in the sample from further hydrolysis or enzymatic degradation, modification, or inactivation; and 4) prolong the conventional time-frame for storage and transportation of the processed sample under a variety of ambient, sub- or supra-optimal temperature conditions to maintain the fidelity and integrity of the released polynucleotides until the biological material can be further processed or analyzed at a diagnostic facility or analytical laboratory.

20. With its patented technology, Longhorn has developed a number of sample collection products, including the PrimeStore® and PrimeExtract™ sample collection products.

SPECTRUM'S INFRINGING ACTIVITY

21. Spectrum develops, manufactures, offers to sell, and/or sells chemical compositions for molecular and diagnostic analysis, particularly aqueous compositions for collection, transport, and storage of a biological specimen containing a population of nucleic acids in a single reaction vessel, which can then be purified and/or analyzed using conventional molecular biology methods. Spectrum is a manufacturer and supplier of such compositions for specimen collection and processing in Utah and other States.

22. Spectrum advertises and sells its products including on its online website, spectrumsolution.com. Spectrum's website advertises two products containing chemicals and solutions used to collect and preserve biological samples for testing: SDNA-1000 and SDNA-2000. Spectrum's website advertises and offers for sale one or more products that, as detailed below, infringe the Asserted Patents, including, without limitation, the SDNA-1000 product (the "Accused Product"). A true and correct copy of an applicable page from Spectrum's website is attached as Exhibit G to this Complaint.

23. Spectrum offers the Accused Product for sale to any and all potential buyers.

24. Spectrum's specification sheet for the Accused Product states that the solution is an "innovative, patented chemistry that preserves & protects both DNA/viral RNA transcripts...." A true and correct copy of Spectrum's specification sheet for the Accused Product is attached as Exhibit H to this Complaint.

25. Upon information and belief, Spectrum has disclosed further information regarding the Accused Product in its two patents directed to nucleic acid preservation solutions: United States Patent No. 10,174,362 ("the '362 Patent") and United States Patent No. 10,774,368 ("the '368 Patent").

26. The '362 Patent discloses in Claim 1, "A human nucleic acid preservation composition." A true and correct copy of the '362 Patent is attached as Exhibit I to this Complaint.

27. The '368 Patent discloses, in Claim 1, "A nucleic acid preservation composition." A true and correct copy of the '368 Patent is attached as Exhibit J to this Complaint.

28. Upon information and belief that is based on the information disclosed in Spectrum's patents and on Spectrum's website, and common knowledge of such chemical compositions to one skilled in the art, the composition of the chemicals and solution used to collect and preserve biological samples for testing used in Spectrum's Accused Product are disclosed in at least one of the '362 Patent or the '368 Patent.

29. Upon information and belief, Spectrum's Accused Product infringes at least one claim of each of the Asserted Patents.

30. Upon information and belief, Spectrum has known of the existence and materiality of the Asserted Patents since at least April 11, 2018 because, inter alia, Spectrum listed one or more of the Asserted Patents on its Information Disclosure Form that it filed with the United States Patent and Trademark Office on April 11, 2018 with respect to Spectrum's prosecution of the application which issued as the '362 Patent.

31. Upon information and belief, Spectrum has known of the existence and materiality of the Asserted Patents as marked on Longhorn's products.

32. Upon information and belief, Spectrum has known of the existence and materiality of the Asserted Patents since at least June 30, 2020 when an investor partner company of Spectrum named DW Healthcare Partners contacted Longhorn on Spectrum's behalf to discuss Longhorn and its products and inquire about a "potential for mutually beneficial partnership" between Longhorn and Spectrum.

FIRST CLAIM FOR RELIEF
(DIRECT INFRINGEMENT OF U.S. PATENT NO. 8,084,443)

33. Longhorn realleges and incorporates by reference, as if fully set forth herein, the allegations of the preceding paragraphs as set forth above.

34. Spectrum has been and is continuing to directly infringe, literally and under the doctrine of equivalents, at least Claims 1, 17, 27, 41, and 47 of the '443 Patent in violation of 35 U.S.C. § 271(a), in this District and elsewhere, by, among other things, making, using, offering to sell, and/or selling at least the Accused Product.

35. For example, Claim 1 of the '443 Patent recites as follows: "An aqueous composition comprising: a) one or more chaotropes; b) one or more detergents; c) one or more reducing agents; d) one or more chelators; and e) one or more buffers, together present in an amount sufficient to denature proteins, inactivate nucleases, kill pathogens, and not degrade nucleic acid of a sample suspected of containing pathogens when the sample is contacted with the composition."

36. The preamble of claim 1 of the '443 Patent claims an aqueous composition.

37. The Accused Product contains an aqueous composition.

38. The Accused Product infringes the preamble of Claim 1 of the '443 Patent.

39. Element (a) of Claim 1 of the '443 Patent claims one or more chaotropes.

40. Upon information and belief, the Accused Product comprises one or more chaotropes, including but not limited to guanidine and/or guanidine thiocyanate.

41. The Accused Product infringes element (a) of Claim 1 of the '443 Patent.

42. Element (b) of Claim 1 of the '433 Patent claims one or more detergents.

43. Upon information and belief, the Accused Product comprises one or more detergents, including but not limited to sodium lauroyl sarcosinate.

44. The Accused Product infringes element (b) of Claim 1 of the '443 Patent.

45. Element (c) of Claim 1 of the '443 Patent claims one or more reducing agents.

46. Upon information and belief, the Accused Product comprises one or more reducing agents, including but not limited to N-acetyl-L-cysteine.

47. The Accused Product infringes element (c) of Claim 1 of the '443 Patent.

48. Element (d) of Claim 1 of the '443 Patent claims one or more chelators.

49. Upon information and belief, the Accused Product comprises one or more chelators, including but not limited to ethylenediaminetetraacetic acid (EDTA) or EDTA disodium (salt) dihydrate.

50. The Accused Product infringes element (d) of Claim 1 of the '443 Patent.

51. Element (e) of Claim 1 of the '443 Patent claims one or more buffers.

52. Upon information and belief, the Accused Product comprises one or more buffers, including but not limited to tris(hydroxymethyl)aminomethane (Tris).

53. The Accused Product infringes element (e) of Claim 1 of the '443 Patent.

54. Claim 1 of the '443 Patent claims that elements (a) through (e) together are present in an amount sufficient to denature proteins, inactivate nucleases, kill pathogens, and not degrade nucleic acid of a sample suspected of containing pathogens when the sample is contacted with the composition.

55. Upon information and belief, the Accused Product is present in an amount capable of denaturing proteins, inactivating nucleases, killing pathogens, without degrading nucleic acid of a sample suspected of containing pathogens when the sample is contacted with the composition.

56. The Accused Product infringes Claim 1 of the '443 patent.

57. Spectrum infringes Claim 1 of the '443 Patent as its Accused Product and the combination of the Accused Product's components embody the patented invention described therein.

58. Spectrum has been and is continuing to directly infringe, literally and under the doctrine of equivalents, at least Claim 1 of the '443 Patent in violation of 35 U.S.C. § 271(a), in this District and elsewhere, by, among other things, making, using and employing a product that embodies the patented invention described in the '443 Patent, offering to sell, and/or selling said Accused Product.

59. Spectrum's acts of making, using, offering to sell, and/or selling the Accused Product has been without the permission, consent, authorization, or license of Longhorn.

60. Spectrum's infringement is willful, wanton, and deliberate, permitting increased damages under 35 U.S.C. § 284 and attorneys' fees and costs incurred under 35 U.S.C. § 285.

61. Upon information and belief, Spectrum will continue to infringe the '443 Patent unless and until it is enjoined by this Court.

62. Spectrum has caused and will continue to cause Longhorn irreparable injury and damage by infringing the '443 Patent. Longhorn will suffer further injury unless and until Spectrum is enjoined from infringing the '443 Patent.

63. Spectrum's infringement of the '443 Patent has injured and continues to injure Longhorn in an amount to be proven at trial, but not less than the amount of a reasonable royalty.

SECOND CLAIM FOR RELIEF
(INDIRECT INFRINGEMENT OF U.S. PATENT NO. 8,084,443)

64. Longhorn realleges and incorporates by reference, as if fully set forth herein, the allegations of the preceding paragraphs as set forth above.

65. In addition to directly infringing the '443 Patent pursuant to 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, or both, Spectrum indirectly infringes at least Claim 4 of the '443 Patent by instructing, directing, and/or requiring others, including its customers, purchasers, and users, to add a sample suspected of containing pathogens to the Accused Product.

66. Longhorn is not aware of any uses of the Accused Product except in connection with the other elements of the patent claims.

67. Upon information and belief, Spectrum has contributed to the infringement of the '443 Patent pursuant to 35 U.S.C. § 271(c) by selling or offering to sell the aqueous composition of the Accused Product that has no substantial non-infringing use and constitutes a material part of the claimed invention, knowing that such component has no substantial use other than a use that directly infringes, either literally or under the doctrine of equivalents, at least Claim 4 of the '443 Patent.

68. Upon information and belief, Spectrum has induced and continues to induce infringement of the '443 Patent pursuant to 35 U.S.C. § 271(b) by instructing, directing, and/or requiring one or more of customers, purchasers, and users of the Accused Product to make, use, sell, offer to sell, or import the Accused Product's aqueous composition with sample, either literally or under the doctrine of equivalents, knowing that such acts if taken would infringe the '443 Patent.

69. Spectrum knew or was willfully blind to the fact that it was contributing to and inducing infringement by others, including customers, purchasers, and users, who were practicing one or more claims of the '443 Patent.

70. Spectrum knowingly and actively aided and abetted the direct infringement of the '443 Patent by instructing and encouraging its customers, purchasers, and users to purchase and use the Accused Product as intended, knowing that such actions if taken would infringe. Such instructions and encouragement included, but are not limited to, advising third parties to purchase and use the Accused Product in an infringing manner, providing a mechanism through which third parties may infringe the '443 Patent, and by advertising and promoting the use of the Accused Product in an infringing manner, and distributing guidelines and instructions to third parties on how to purchase and use the Accused Product in an infringing manner.

71. Spectrum's indirect infringement is willful, wanton, and deliberate, permitting increased damages under 35 U.S.C. § 284 and attorneys' fees and costs incurred under 35 U.S.C. § 285.

72. Spectrum's indirect infringement of the '443 Patent has injured and continues to injure Longhorn in an amount to be proven at trial, but not less than a reasonable royalty.

THIRD CLAIM FOR RELIEF
(DIRECT INFRINGEMENT OF U.S. PATENT NO. 8,293,467)

73. Longhorn realleges and incorporates by reference, as if fully set forth herein, the allegations of the preceding paragraphs as set forth above.

74. Spectrum has been and is continuing to directly infringe, literally and under the doctrine of equivalents, at least Claims 1 and 29 of the '467 Patent in violation of 35 U.S.C. § 271(a), in this District and elsewhere, by, among other things, making, using, offering to sell, and/or selling at least the Accused Product.

75. For example, Claim 1 of the '467 Patent recites as follows: "A method for denaturing proteins, inactivating nucleases and killing pathogens in one step without degrading

nucleic acid of a biological sample containing proteins, nucleases, and nucleic acid, and suspected to contain pathogens, comprising: providing a mixture containing one or more chaotropes, one or more detergents, one or more reducing agents, one or more chelators, and one or more buffers, together present in an amount sufficient to denature proteins, inactivate nucleases, kill pathogens, and not degrade nucleic acid; contacting the biological sample with the mixture which denatures proteins, inactivate nucleases, kill pathogens, and does not degrade nucleic acid of the biological sample; and detecting the presence and identity of or absence of the pathogens in the biological sample.”

76. The preamble of claim 1 of the '467 Patent claims a method for denaturing proteins, inactivating nucleases and killing pathogens in one step without degrading nucleic acid of a biological sample containing proteins, nucleases, and nucleic acid, and suspected to contain pathogens.

77. Upon information and belief, Spectrum practices a method of denaturing proteins, inactivating nucleases and killing pathogens in one step without degrading nucleic acid of a biological sample containing proteins, nucleases, and nucleic acid, and suspected to contain pathogens.

78. Spectrum practices the preamble of Claim 1 of the '467 Patent.

79. Element (a) of Claim 1 of the '467 Patent claims providing a mixture containing one or more chaotropes, one or more detergents, one or more reducing agents, one or more chelators, and one or more buffers, together present in an amount sufficient to denature proteins, inactivate nucleases, kill pathogens, and not degrade nucleic acid.

80. Upon information and belief, Spectrum provides a mixture containing one or more chaotropes, including but not limited to guanidine and/or guanidine thiocyanate, one or more detergents, including but not limited to sodium lauroyl sarcosinate, one or more reducing agents, including but not limited to N-acetyl-L-cysteine, one or more chelators, including but not limited to ethylenediaminetetraacetic acid (EDTA) or EDTA disodium (salt) dehydrate, and one or more buffers, including but not limited to % tris(hydroxymethyl)aminomethane (Tris), together present in an amount sufficient to denature proteins, inactivate nucleases, kill pathogens, and not degrade nucleic acid.

81. Spectrum practices element (a) of Claim 1 of the '467 Patent.

82. Element (b) of Claim 1 of the '467 Patent claims contacting the biological sample with the mixture which denatures proteins, inactivates nucleases, kills pathogens, and does not degrade nucleic acid of the biological sample.

83. Upon information and belief, Spectrum contacts the biological sample with the mixture which denatures proteins, inactivates nucleases, kills pathogens, and does not degrade nucleic acid of the biological sample.

84. Spectrum practices element (b) of Claim 1 of the '467 Patent.

85. Element (c) of Claim 1 of the '467 Patent claims detecting the presence and identity of or absence of the pathogens in the biological sample.

86. Upon information and belief, Spectrum detects the presence and identity of or absence of the pathogens in the biological sample.

87. Spectrum practices element (c) of Claim 1 of the '467 Patent.

88. Spectrum practices Claim 1 of the '467 patent.

89. Spectrum infringes Claim 1 of the '467 Patent as its method embodies the patented invention described therein.

90. Spectrum has been and is continuing to directly infringe, literally and under the doctrine of equivalents, at least Claim 1 of the '467 Patent in violation of 35 U.S.C. § 271(a), in this District and elsewhere, by, among other things, making, using and employing a method that embodies the patented invention described in the '467 Patent, offering to sell, and/or selling said method. Spectrum's acts of making, using, offering to sell, and/or selling the method has been without the permission, consent, authorization, or license of Longhorn.

91. Spectrum's acts of making, using, offering to sell, and/or selling the Accused Product has been without the permission, consent, authorization, or license of Longhorn.

92. Spectrum's infringement is willful, wanton, and deliberate, permitting increased damages under 35 U.S.C. § 284 and attorneys' fees and costs incurred under 35 U.S.C. § 285.

93. Upon information and belief, Spectrum will continue to infringe the '467 Patent unless and until it is enjoined by this Court.

94. Spectrum has caused and will continue to cause Longhorn irreparable injury and damage by infringing the '467 Patent. Longhorn will suffer further injury unless and until Spectrum is enjoined from infringing the '467 Patent.

95. Spectrum's infringement of the '467 Patent has injured and continues to injure Longhorn in an amount to be proven at trial, but not less than the amount of a reasonable royalty.

FOURTH CLAIM FOR RELIEF
(INDIRECT INFRINGEMENT OF U.S. PATENT NO. 8,293,467)

96. Longhorn realleges and incorporates by reference, as if fully set forth herein, the allegations of the preceding paragraphs as set forth above.

97. In addition to directly infringing the '467 Patent pursuant to 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, or both, Spectrum indirectly infringes at least Claim 1 of the '467 Patent by instructing, directing, and/or requiring others, including its customers, purchasers, and users, to contact a biological sample with the mixture which denatures proteins, inactivate nucleases, kill pathogens, and does not degrade nucleic acid of the biological sample and/or detecting the presence and identity of or absence of the pathogens in the biological sample.

98. Longhorn is not aware of any uses of the Accused Product except in connection with the other elements of the patent claims.

99. Upon information and belief, Spectrum has contributed to the infringement of the '467 Patent pursuant to 35 U.S.C. § 271(c) by providing a mixture containing one or more chaotropes, one or more detergents, one or more reducing agents, one or more chelators, and one or more buffers, together present in an amount sufficient to denature proteins, inactivate nucleases, kill pathogens, and not degrade nucleic acid that has no substantial non-infringing use and constitutes a material part of the claimed invention, knowing that such component has no substantial use other than a use that directly infringes, either literally or under the doctrine of equivalents, at least Claim 1 of the '467 Patent.

100. Upon information and belief, Spectrum has induced and continues to induce infringement of the '467 Patent pursuant to 35 U.S.C. § 271(b) by instructing, directing, and/or requiring one or more of customers, purchasers, and users of the Accused Product to make, use, sell, offer to sell, or import the method of contacting a biological sample with the mixture which denatures proteins, inactivate nucleases, kill pathogens, and does not degrade nucleic acid of the

biological sample and/or detecting the presence and identity of or absence of the pathogens in the biological sample, either literally or under the doctrine of equivalents, knowing that such acts if taken would infringe the '467 Patent.

101. Spectrum knew or was willfully blind to the fact that it was contributing to and inducing infringement by others, including customers, purchasers, and users, who were practicing one or more claims of the '467 Patent.

102. Spectrum knowingly and actively aided and abetted the direct infringement of the '467 Patent by instructing and encouraging its customers, purchasers, and users to purchase and use the Accused Product as intended, knowing that such actions if taken would infringe. Such instructions and encouragement included, but are not limited to, advising third parties to purchase and use the Accused Product in an infringing manner, providing a mechanism through which third parties may infringe the '467 Patent, and by advertising and promoting the use of the Accused Products in an infringing manner, and distributing guidelines and instructions to third parties on how to purchase and use the Accused Product in an infringing manner.

103. Spectrum's indirect infringement is willful, wanton, and deliberate, permitting increased damages under 35 U.S.C. § 284 and attorneys' fees and costs incurred under 35 U.S.C. § 285.

104. Spectrum's indirect infringement of the '467 Patent has injured and continues to injure Longhorn in an amount to be proven at trial, but not less than a reasonable royalty.

FIFTH CLAIM FOR RELIEF
(DIRECT INFRINGEMENT OF U.S. PATENT NO. 8,415,330)

105. Longhorn realleges and incorporates by reference, as if fully set forth herein, the allegations of the preceding paragraphs as set forth above.

106. Spectrum has been and is continuing to directly infringe, literally and under the doctrine of equivalents, at least Claims 1, 31, and 38 of the '330 Patent in violation of 35 U.S.C. § 271(a), in this District and elsewhere, by, among other things, making, using, offering to sell, and/or selling at least the Accused Product.

107. For example, Claim 1 of the '330 Patent recites as follows: "An aqueous composition that comprises: a chaotrope; a detergent; a chelator; a reducing agent; nuclease-free water, and a buffer with a pH of about 5 to about 7, wherein upon contact of the composition at ambient temperature with a biological sample suspected of containing a pathogen, nucleic acids and other macromolecules, creates an effective concentration of the composition that, in one step, disinfects said sample, inactivates nucleases of said sample, and extracts the nucleic acids from the other macromolecules such that a target sequence of the nucleic acids is detectable by a nucleic acid test."

108. Preamble of claim 1 of the '330 Patent claims an aqueous composition.

109. Upon information and belief, the Accused Product is an aqueous carrier.

110. The Accused Product infringes the preamble of Claim 1 of the '330 Patent.

111. Element (a) of Claim 1 of the '330 Patent claims a chaotrope.

112. Upon information and belief, the Accused Product comprises a chaotrope, including but not limited to guanidine and/or guanidine thiocyanate.

113. The Accused Product infringes element (a) of Claim 1 of the '330 Patent.

114. Element (b) of Claim 1 of the '330 Patent claims a detergent.

115. Upon information and belief, the Accused Product comprises a detergent, including but not limited to sodium lauroyl sarcosinate.

116. The Accused Product infringes element (b) of Claim 1 of the '330 Patent.

117. Element (c) of Claim 1 of the '330 Patent claims a chelator.

118. Upon information and belief, the Accused Product comprises a chelator, including but not limited to ethylenediaminetetraacetic acid (EDTA) or EDTA disodium (salt) dehydrate.

119. The Accused Product infringes element (c) of Claim 1 of the '330 Patent.

120. Element (d) of Claim 1 of the '330 Patent claims a reducing agent.

121. Upon information and belief, the Accused Product comprises a reducing agents, including but not limited to N-acetyl-L-cysteine.

122. The Accused Product infringes element (d) of Claim 1 of the '330 Patent.

123. Element (e) of Claim 1 of the '330 Patent claims nuclease-free water.

124. Upon information and belief, the Accused Product comprises nuclease-free water.

125. The Accused Product infringes element (e) of Claim 1 of the '330 Patent.

126. Element (f) of Claim 1 of the '330 Patent claims a buffer with a pH of about 5 to about 7.

127. Upon information and belief, the Accused Product comprises a buffer, including but not limited to tris(hydroxymethyl)aminomethane (Tris), with a pH of about 5 to about 7.

128. The Accused Product infringes element (f) of Claim 1 of the '330 Patent.

129. Claim 1 of the '330 Patent claims that elements (a) through (f) that upon contact of the composition at ambient temperature with a biological sample suspected of containing a pathogen, nucleic acids and other macromolecules, creates an effective concentration of the composition that, in one step, disinfects said sample, inactivates nucleases of said sample, and

extracts the nucleic acids from the other macromolecules such that a target sequence of the nucleic acids is detectable by a nucleic acid test.

130. Upon information and belief, the Accused Product upon contact of the composition at ambient temperature with a biological sample suspected of containing a pathogen, nucleic acids and other macromolecules, creates an effective concentration of the composition that, in one step, disinfects said sample, inactivates nucleases of said sample, and extracts the nucleic acids from the other macromolecules such that a target sequence of the nucleic acids is detectable by a nucleic acid test.

131. The Accused Product infringes Claim 1 of the '330 patent.

132. Spectrum infringes Claim 1 of the '330 Patent as its Accused Product and the combination of the Accused Product's components embody the patented invention described therein.

133. Spectrum has been and is continuing to directly infringe, literally and under the doctrine of equivalents, at least Claim 1 of the '330 Patent in violation of 35 U.S.C. § 271(a), in this District and elsewhere, by, among other things, making, using and employing a method that embodies the patented invention described in the '330 Patent, offering to sell, and/or selling said method. Spectrum's acts of making, using, offering to sell, and/or selling the method has been without the permission, consent, authorization, or license of Longhorn.

134. Spectrum's acts of making, using, offering to sell, and/or selling the Accused Product has been without the permission, consent, authorization, or license of Longhorn.

135. Spectrum's infringement is willful, wanton, and deliberate, permitting increased damages under 35 U.S.C. § 284 and attorneys' fees and costs incurred under 35 U.S.C. § 285.

136. Upon information and belief, Spectrum will continue to infringe the '330 Patent unless and until it is enjoined by this Court.

137. Spectrum has caused and will continue to cause Longhorn irreparable injury and damage by infringing the '330 Patent. Longhorn will suffer further injury unless and until Spectrum is enjoined from infringing the '330 Patent.

138. Spectrum's infringement of the '330 Patent has injured and continues to injure Longhorn in an amount to be proven at trial, but not less than the amount of a reasonable royalty.

SIXTH CLAIM FOR RELIEF
(INDIRECT INFRINGEMENT OF U.S. PATENT NO. 8,415,330)

139. Longhorn realleges and incorporates by reference, as if fully set forth herein, the allegations of the preceding paragraphs as set forth above.

140. In addition to directly infringing the '330 Patent pursuant to 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, or both, Spectrum indirectly infringes the '330 Patent by instructing, directing, and/or requiring others, including its customers, purchasers, and users, to perform one or more of the claims.

141. Longhorn is not aware of any uses of the Accused Product except in connection with the other elements of the patent claims.

142. In addition to directly infringing the '330 Patent pursuant to 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, or both, Spectrum indirectly infringes at least Claim 1 of the '330 Patent by instructing, directing, and/or requiring others, including its customers, purchasers, and users, to contact a biological sample suspected of containing a pathogen, nucleic acids and other macromolecules with the Accused Product.

143. Longhorn is not aware of any uses of the Accused Product except in connection with the other elements of the patent claims.

144. Upon information and belief, Spectrum has contributed to the infringement of the '330 Patent pursuant to 35 U.S.C. § 271(c) by selling or offering to sell the aqueous composition of the Accused Product that has no substantial non-infringing use and constitutes a material part of the claimed invention, knowing that such component has no substantial use other than a use that directly infringes, either literally or under the doctrine of equivalents, at least Claim 1 of the '330 Patent.

145. Upon information and belief, Spectrum has induced and continues to induce infringement of the '330 Patent pursuant to 35 U.S.C. § 271(b) by instructing, directing, and/or requiring one or more of customers, purchasers, and users of the Accused Product to make, use, sell, offer to sell, or import the Accused Product's aqueous composition with a biological sample, either literally or under the doctrine of equivalents, knowing that such acts if taken would infringe the '330 Patent.

146. Spectrum knew or was willfully blind to the fact that it was contributing to and inducing infringement by others, including customers, purchasers, and users, who were practicing one or more claims of the '330 Patent.

147. Spectrum knowingly and actively aided and abetted the direct infringement of the '330 Patent by instructing and encouraging its customers, purchasers, and users to purchase and use the Accused Product as intended, knowing that such actions if taken would infringe. Such instructions and encouragement included, but are not limited to, advising third parties to purchase and use the Accused Product in an infringing manner, providing a mechanism through

which third parties may infringe the '330 Patent, and by advertising and promoting the use of the Accused Products in an infringing manner, and distributing guidelines and instructions to third parties on how to purchase and use the Accused Product in an infringing manner.

148. Spectrum's indirect infringement is willful, wanton, and deliberate, permitting increased damages under 35 U.S.C. § 284 and attorneys' fees and costs incurred under 35 U.S.C. § 285.

149. Spectrum's indirect infringement of the '330 Patent has injured and continues to injure Longhorn in an amount to be proven at trial, but not less than a reasonable royalty.

SEVENTH CLAIM FOR RELIEF
(DIRECT INFRINGEMENT OF U.S. PATENT NO. 8,669,240)

150. Longhorn realleges and incorporates by reference, as if fully set forth herein, the allegations of the preceding paragraphs as set forth above.

151. Spectrum has been and is continuing to directly infringe, literally and under the doctrine of equivalents, at least Claims 1, 21, 32, and 35 of the '240 Patent in violation of 35 U.S.C. § 271(a), in this District and elsewhere, by, among other things, making, using, offering to sell, and/or selling at least the Accused Product.

152. For example, Claim 1 of the '240 Patent recites as follows: "An aqueous composition comprising: a) one or more chaotropes; b) one or more detergents; c) one or more reducing agents; d) one or more chelators; and e) one or more buffers, together present in an amount sufficient to denature one or more proteins, inactivate one or more nucleases, kill one or more pathogens, or prevent one or more nucleic acids from degrading in a sample suspected of containing nucleic acids, when the sample is contacted with the composition."

153. The preamble of claim 1 of the '240 Patent claims an aqueous composition.

154. The Accused Product contains an aqueous composition.
155. The Accused Product practices the preamble of Claim 1 of the '240 Patent.
156. Element (a) of Claim 1 of the '240 Patent claims one or more chaotropes.
157. Upon information and belief, the Accused Product comprises one or more chaotropes, including but not limited to guanidine and/or guanidine thiocyanate.
158. The Accused Product practices element (a) of Claim 1 of the '240 Patent.
159. Element (b) of Claim 1 of the '240 Patent claims one or more detergents.
160. Upon information and belief, the Accused Product comprises one or more detergents, including but not limited to sodium lauroyl sarcosinate.
161. The Accused Product practices element (b) of Claim 1 of the '240 Patent.
162. Element (c) of Claim 1 of the '240 Patent claims one or more reducing agents.
163. Upon information and belief, the Accused Product comprises one or more reducing agents, including but not limited to N-acetyl-L-cysteine.
164. The Accused Product practices element (c) of Claim 1 of the '240 Patent.
165. Element (d) of Claim 1 of the '240 Patent claims one or more chelators.
166. Upon information and belief, the Accused Product comprises one or more chelators, including but not limited to ethylenediaminetetraacetic acid (EDTA) or EDTA disodium (salt) dihydrate.
167. The Accused Product practices element (d) of Claim 1 of the '240 Patent.
168. Element (e) of Claim 1 of the '240 Patent claims one or more buffers.
169. Upon information and belief, the Accused Product comprises one or more buffers, including but not limited to tris(hydroxymethyl)aminomethane (Tris).

170. The Accused Product practices element (e) of Claim 1 of the '240 Patent.

171. Claim 1 of the '240 Patent claims that elements (a) through (e) together are present in an amount sufficient to denature one or more proteins, inactivate one or more nucleases, kill one or more pathogens, or prevent one or more nucleic acids from degrading in a sample suspected of containing nucleic acids, when the sample is contacted with the composition.

172. Upon information and belief, the Accused Product is present in an amount capable of denaturing one or more proteins, inactivate one or more nucleases, kill one or more pathogens, or prevent one or more nucleic acids from degrading in a sample suspected of containing nucleic acids, when the sample is contacted with the composition.

173. The Accused Product practices Claim 1 of the '240 patent.

174. Spectrum infringes Claim 1 of the '240 Patent as its Infringing Products, and the combination of its components, embody the patented invention described therein.

175. Spectrum has been and is continuing to directly infringe, literally and under the doctrine of equivalents, at least Claim 1 of the '240 Patent in violation of 35 U.S.C. § 271(a), in this District and elsewhere, by, among other things, making, using and employing a product that embodies the patented invention described in the '240 Patent, offering to sell, and/or selling said Accused Product.

176. Spectrum's acts of making, using, offering to sell, and/or selling the Accused Product has been without the permission, consent, authorization, or license of Longhorn.

177. Spectrum's infringement is willful, wanton, and deliberate, permitting increased damages under 35 U.S.C. § 284 and attorneys' fees and costs incurred under 35 U.S.C. § 285.

178. Upon information and belief, Spectrum will continue to infringe the '240 Patent unless and until it is enjoined by this Court.

179. Spectrum has caused and will continue to cause Longhorn irreparable injury and damage by infringing the '240 Patent. Longhorn will suffer further injury unless and until Spectrum is enjoined from infringing the '240 Patent.

180. Spectrum's infringement of the '240 Patent has injured and continues to injure Longhorn in an amount to be proven at trial, but not less than the amount of a reasonable royalty.

EIGHTH CLAIM FOR RELIEF
(INDIRECT INFRINGEMENT OF U.S. PATENT NO. 8,669,240)

181. Longhorn realleges and incorporates by reference, as if fully set forth herein, the allegations of the preceding paragraphs as set forth above.

182. In addition to directly infringing the '240 Patent pursuant to 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, or both, Spectrum indirectly infringes at least Claim 16 of the '240 Patent by instructing, directing, and/or requiring others, including its customers, purchasers, and users, to add a population of isolated polynucleotides that comprises RNA, DNA, or a combination thereof to the Accused Product.

183. Longhorn is not aware of any uses of the Accused Product except in connection with the other elements of the patent claims.

184. Upon information and belief, Spectrum has contributed to the infringement of the '240 Patent pursuant to 35 U.S.C. § 271(c) by selling or offering to sell the aqueous composition of the Accused Product that has no substantial non-infringing use and constitutes a material part of the claimed invention, knowing that such component has no substantial use other than a use

that directly infringes, either literally or under the doctrine of equivalents, at least Claim 16 of the '240 Patent.

185. Upon information and belief, Spectrum has induced and continues to induce infringement of the '240 Patent pursuant to 35 U.S.C. § 271(b) by instructing, directing, and/or requiring one or more of customers, purchasers, and users of the Accused Product to make, use, sell, offer to sell, or import the Accused Product's aqueous composition with a population of isolated polynucleotides that comprises RNA, DNA, or a combination thereof, either literally or under the doctrine of equivalents, knowing that such acts if taken would infringe the '240 Patent.

186. Spectrum knew or was willfully blind to the fact that it was contributing to and inducing infringement by others, including customers, purchasers, and users, who were practicing one or more claims of the '240 Patent.

187. Spectrum knowingly and actively aided and abetted the direct infringement of the '240 Patent by instructing and encouraging its customers, purchasers, and users to purchase and use the Accused Product as intended, knowing that such actions if taken would infringe. Such instructions and encouragement included, but are not limited to, advising third parties to purchase and use the Accused Product in an infringing manner, providing a mechanism through which third parties may infringe the '240 Patent, and by advertising and promoting the use of the Accused Products in an infringing manner, and distributing guidelines and instructions to third parties on how to purchase and use the Accused Product in an infringing manner.

188. Spectrum's indirect infringement is willful, wanton, and deliberate, permitting increased damages under 35 U.S.C. § 284 and attorneys' fees and costs incurred under 35 U.S.C. § 285.

189. Spectrum's indirect infringement of the '240 Patent has injured and continues to injure Longhorn in an amount to be proven at trial, but not less than a reasonable royalty.

NINTH CLAIM FOR RELIEF
(DIRECT INFRINGEMENT OF U.S. PATENT NO. 9,212,399)

190. Longhorn realleges and incorporates by reference, as if fully set forth herein, the allegations of the preceding paragraphs as set forth above.

191. Spectrum has been and is continuing to directly infringe, literally and under the doctrine of equivalents, at least Claims 1, 21, 33, and 35 of the '399 Patent in violation of 35 U.S.C. § 271(a), in this District and elsewhere, by, among other things, making, using, offering to sell, and/or selling at least the Accused Product.

192. For example, Claim 1 of the '399 Patent recites as follows: "A stock solution of an aqueous composition comprising: a chaotrope; a detergent; a reducing agent; a chelator; and a buffer, wherein the stock composition, when diluted with a sample containing nucleic acids, nucleases and proteins, denatures the proteins of the sample, inactivates the nucleases of the sample, kills pathogens that may be present in the sample, and does not degrade the nucleic acids of the sample."

193. The preamble of claim 1 of the '399 Patent claims a stock solution of an aqueous composition.

194. The Accused Product contains a stock solution of an aqueous composition.

195. The Accused Product practices the preamble of Claim 1 of the '399 Patent.

196. Element (a) of Claim 1 of the '399 Patent claims a chaotrope.

197. Upon information and belief, the Accused Product a chaotrope, including but not limited to guanidine and/or guanidine thiocyanate.

198. The Accused Product practices element (a) of Claim 1 of the '399 Patent.

199. Element (b) of Claim 1 of the '399 Patent claims a detergent.

200. Upon information and belief, the Accused Product comprises a detergent, including but not limited to sodium lauroyl sarcosinate.

201. The Accused Product practices element (b) of Claim 1 of the '399 Patent.

202. Element (c) of Claim 1 of the '399 Patent claims a reducing agent.

203. Upon information and belief, the Accused Product comprises a reducing agent, including but not limited to N-acetyl-L-cysteine.

204. The Accused Product practices element (c) of Claim 1 of the '399 Patent.

205. Element (d) of Claim 1 of the '399 Patent claims a chelator.

206. Upon information and belief, the Accused Product comprises a chelator, including but not limited to ethylenediaminetetraacetic acid (EDTA) or EDTA disodium (salt) dihydrate.

207. The Accused Product practices element (d) of Claim 1 of the '399 Patent.

208. Element (e) of Claim 1 of the '399 Patent claims a buffer.

209. Upon information and belief, the Accused Product comprises a buffer, including but not limited to tris(hydroxymethyl)aminomethane (Tris).

210. The Accused Product practices element (e) of Claim 1 of the '399 Patent.

211. Claim 1 of the '399 Patent claims that elements (a) through (e) together are present such that the stock composition, when diluted with a sample containing nucleic acids, nucleases and proteins, denatures the proteins of the sample, inactivates the nucleases of the sample, kills pathogens that may be present in the sample, and does not degrade the nucleic acids of the sample.

212. Upon information and belief, the Accused Product is present such that, when diluted with a sample containing nucleic acids, nucleases and proteins, denatures the proteins of the sample, inactivates the nucleases of the sample, kills pathogens that may be present in the sample, and does not degrade the nucleic acids of the sample.

213. The Accused Product infringes Claim 1 of the '399 patent.

214. Spectrum infringes Claim 1 of the '399 Patent as its Accused Product and the combination of the Accused Product's components embody the patented invention described therein.

215. Spectrum has been and is continuing to directly infringe, literally and under the doctrine of equivalents, at least Claim 1 of the '399 Patent in violation of 35 U.S.C. § 271(a), in this District and elsewhere, by, among other things, making, using and employing a product that embodies the patented invention described in the '399 Patent, offering to sell, and/or selling said Accused Product.

216. Spectrum's acts of making, using, offering to sell, and/or selling the Accused Product has been without the permission, consent, authorization, or license of Longhorn.

217. Spectrum's infringement is willful, wanton, and deliberate, permitting increased damages under 35 U.S.C. § 284 and attorneys' fees and costs incurred under 35 U.S.C. § 285.

218. Upon information and belief, Spectrum will continue to infringe the '399 Patent unless and until it is enjoined by this Court.

219. Spectrum has caused and will continue to cause Longhorn irreparable injury and damage by infringing the '399 Patent. Longhorn will suffer further injury unless and until Spectrum is enjoined from infringing the '399 Patent.

220. Spectrum's infringement of the '399 Patent has injured and continues to injure Longhorn in an amount to be proven at trial, but not less than the amount of a reasonable royalty.

TENTH CLAIM FOR RELIEF
(INDIRECT INFRINGEMENT OF U.S. PATENT NO. 9,212,399)

221. Longhorn realleges and incorporates by reference, as if fully set forth herein, the allegations of the preceding paragraphs as set forth above.

222. In addition to directly infringing the '399 Patent pursuant to 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, or both, Spectrum indirectly infringes at least Claim 1 of the '399 Patent by instructing, directing, and/or requiring others, including its customers, purchasers, and users to dilute the Accused Product with a sample containing nucleic acids, nucleases and proteins.

223. Longhorn is not aware of any uses of the Accused Product except in connection with the other elements of the patent claims.

224. Upon information and belief, Spectrum has contributed to the infringement of the '399 Patent pursuant to 35 U.S.C. § 271(c) by selling or offering to sell the stock solution of an aqueous composition of the Accused Product that has no substantial non-infringing use and constitutes a material part of the claimed invention, knowing that such component has no substantial use other than a use that directly infringes, either literally or under the doctrine of equivalents, at least Claim 1 of the '399 Patent.

225. Upon information and belief, Spectrum has induced and continues to induce infringement of the '399 Patent pursuant to 35 U.S.C. § 271(b) by instructing, directing, and/or requiring one or more of customers, purchasers, and users of the Accused Product to make, use, sell, offer to sell, or import the Accused Product's stock solution of an aqueous composition with

a sample containing nucleic acids, nucleases and proteins, either literally or under the doctrine of equivalents, knowing that such acts if taken would infringe the '399 Patent.

226. Spectrum knew or was willfully blind to the fact that it was contributing to and inducing infringement by others, including customers, purchasers, and users, who were practicing one or more claims of the '399 Patent.

227. Spectrum knowingly and actively aided and abetted the direct infringement of the '399 Patent by instructing and encouraging its customers, purchasers, and users to purchase and use the Accused Product as intended, knowing that such actions if taken would infringe. Such instructions and encouragement included, but are not limited to, advising third parties to purchase and use the Accused Product in an infringing manner, providing a mechanism through which third parties may infringe the '399 Patent, and by advertising and promoting the use of the Accused Products in an infringing manner, and distributing guidelines and instructions to third parties on how to purchase and use the Accused Product in an infringing manner.

228. Spectrum's indirect infringement is willful, wanton, and deliberate, permitting increased damages under 35 U.S.C. § 284 and attorneys' fees and costs incurred under 35 U.S.C. § 285.

229. Spectrum's indirect infringement of the '399 Patent has injured and continues to injure Longhorn in an amount to be proven at trial, but not less than a reasonable royalty.

ELEVENTH CLAIM FOR RELIEF
(DIRECT INFRINGEMENT OF U.S. PATENT NO. 9,683,256)

230. Longhorn realleges and incorporates by reference, as if fully set forth herein, the allegations of the preceding paragraphs as set forth above.

231. Spectrum has been and is continuing to directly infringe, literally and under the doctrine of equivalents, at least Claims 1, 15, and 17 of the '256 Patent in violation of 35 U.S.C. § 271(a), in this District and elsewhere, by, among other things, making, using, offering to sell, and/or selling at least the Accused Product.

232. For example, Claim 1 of the '256 Patent recites as follows: "A stock solution comprising components with concentrations as follows: a chaotrope present in an amount from 0.5 M to 6M; a detergent present in an amount from 0.1% to 1% (wt./vol.); a reducing agent in an amount from 0.5 mM to 0.3 M; a chelator present in an amount from 0.01 mM to 50 mM; a surfactant present in an amount from 0.0001% to 0.3% (wt./vol.); a short-chain alkanol present in an amount from 1 to 25% (vol./vol.); a buffer present in an amount from 1 mM to 1 M; an acid or base present in an amount that provides a pH of from 5 to 7 to the stock solution; and nuclease-free water, wherein the stock solution, when combined with a biological sample suspected of containing a pathogen, denatures proteins, inactivates nucleases, and kills pathogens all without degrading nucleic acids of the sample."

233. The preamble of claim 1 of the '256 Patent claims a stock solution.

234. The Accused Product contains a stock solution.

235. The Accused Product infringes the preamble of Claim 1 of the '256 Patent.

236. Element (a) of Claim 1 of the '256 Patent claims a chaotrope present in an amount from 0.5 M to 6M.

237. Upon information and belief, the Accused Product comprises a chaotrope present in an amount from 0.5 M to 6M, including but not limited to guanidine and/or guanidine thiocyanate present in an amount of 3.3455 – 4.088M.

238. The Accused Product infringes element (a) of Claim 1 of the '256 Patent.

239. Element (b) of Claim 1 of the '256 Patent a detergent present in an amount from 0.1% to 1% (wt./vol.).

240. Upon information and belief, the Accused Product comprises a detergent present in an amount from 0.1% to 1% (wt./vol.), including but not limited to sodium lauroyl sarcosinate present in an amount of 0.251% - 0.307%.

241. The Accused Product infringes element (b) of Claim 1 of the '256 Patent.

242. Element (c) of Claim 1 of the '256 Patent claims a reducing agent in an amount from 0.5 mM to 0.3 M.

243. Upon information and belief, the Accused Product comprises a reducing agent in an amount from 0.5 mM to 0.3 M, including but not limited to N-acetyl-L-cysteine in an amount of 0.51 mM to 10.46 mM.

244. The Accused Product infringes element (c) of Claim 1 of the '256 Patent.

245. Element (d) of Claim 1 of the '256 Patent claims a chelator present in an amount from 0.01 mM to 50 mM.

246. Upon information and belief, the Accused Product comprises a chelator present in an amount from 0.01 mM to 50 mM, including but not limited to ethylenediaminetetraacetic acid (EDTA) or EDTA disodium (salt) dehydrate present in an amount of 0.73%-0.89%.

247. The Accused Product infringes element (d) of Claim 1 of the '256 Patent.

248. Element (e) of Claim 1 of the '256 Patent claims a surfactant present in an amount from 0.0001% to 0.3% (wt./vol.).

249. Upon information and belief, the Accused Product comprises a surfactant present in an amount from 0.0001% to 0.3% (wt./vol), including but not limited to sodium lauroyl sarcosinate present in an amount of 0.251% - 0.307%.

250. The Accused Product infringes element (e) of Claim 1 of the '256 Patent.

251. Element (f) of Claim 1 of the '256 Patent claims a short-chain alkanol present in an amount from 1 to 25% (vol./vol.).

252. Upon information and belief, the Accused Product comprises a short-chain alkanol present in an amount from 1 to 25% (vol./vol.), including but not limited to alcohol comprising ethanol present in an amount of 15.96% - 19.50%.

253. The Accused Product infringes element (f) of Claim 1 of the '256 Patent.

254. Element (g) of Claim 1 of the '256 Patent claims a buffer present in an amount from 1 mM to 1 M.

255. Upon information and belief, the Accused Product comprises a buffer present in an amount from 1 mM to 1 M, including but not limited to tris(hydroxymethyl)aminomethane (Tris) present in an amount of 81.78 mM 99.9 mM.

256. The Accused Product infringes element (g) of Claim 1 of the '256 Patent.

257. Element (h) of Claim 1 of the '256 Patent claims an acid or base present in an amount that provides a pH of from 5 to 7 to the stock solution.

258. Upon information and belief, the Accused Product comprises an acid or base, including but not limited to hydrochloric acid qs, present in an amount that provides a pH of from 5 to 7 to the stock solution.

259. The Accused Product infringes element (h) of Claim 1 of the '256 Patent.

260. Element (i) of Claim 1 of the '256 Patent claims nuclease-free water.

261. Upon information and belief, the Accused Product comprises nuclease-free water.

262. The Accused Product infringes element (i) of Claim 1 of the '256 Patent.

263. Claim 1 of the '256 Patent claims that elements (a) through (i) together are present wherein the stock solution, when combined with a biological sample suspected of containing a pathogen, denatures proteins, inactivates nucleases, and kills pathogens all without degrading nucleic acids of the sample.

264. Upon information and belief, the Accused Product's stock solution, when combined with a biological sample suspected of containing a pathogen, denatures proteins, inactivates nucleases, and kills pathogens all without degrading nucleic acids of the sample.

265. The Accused Product infringes Claim 1 of the '256 patent.

266. Spectrum infringes Claim 1 of the '256 Patent as its Accused Product and the combination of the Accused Product's components embody the patented invention described therein.

267. Spectrum has been and is continuing to directly infringe, literally and under the doctrine of equivalents, at least Claim 1 of the '256 Patent in violation of 35 U.S.C. § 271(a), in this District and elsewhere, by, among other things, making, using and employing a product that embodies the patented invention described in the '256 Patent, offering to sell, and/or selling said Accused Product.

268. Spectrum's acts of making, using, offering to sell, and/or selling the Accused Product has been without the permission, consent, authorization, or license of Longhorn.

269. Spectrum's infringement is willful, wanton, and deliberate, permitting increased damages under 35 U.S.C. § 284 and attorneys' fees and costs incurred under 35 U.S.C. § 285.

270. Upon information and belief, Spectrum will continue to infringe the '256 Patent unless and until it is enjoined by this Court.

271. Spectrum has caused and will continue to cause Longhorn irreparable injury and damage by infringing the '256 Patent. Longhorn will suffer further injury unless and until Spectrum is enjoined from infringing the '256 Patent.

272. Spectrum's infringement of the '256 Patent has injured and continues to injure Longhorn in an amount to be proven at trial, but not less than the amount of a reasonable royalty.

TWELFTH CLAIM FOR RELIEF
(INDIRECT INFRINGEMENT OF U.S. PATENT NO. 9,683,256)

273. Longhorn realleges and incorporates by reference, as if fully set forth herein, the allegations of the preceding paragraphs as set forth above.

274. In addition to directly infringing the '256 Patent pursuant to 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, or both, Spectrum indirectly infringes at least Claim 1 of the '256 Patent by instructing, directing, and/or requiring others, including its customers, purchasers, and users to combine the Accused Product with a biological sample suspected of containing a pathogen.

275. Longhorn is not aware of any uses of the Accused Product except in connection with the other elements of the patent claims.

276. Upon information and belief, Spectrum has contributed to the infringement of the '256 Patent pursuant to 35 U.S.C. § 271(c) by selling or offering to sell the stock solution of the Accused Product that has no substantial non-infringing use and constitutes a material part of the

claimed invention, knowing that such component has no substantial use other than a use that directly infringes, either literally or under the doctrine of equivalents, at least Claim 1 of the '256 Patent.

277. Upon information and belief, Spectrum has induced and continues to induce infringement of the '256 Patent pursuant to 35 U.S.C. § 271(b) by instructing, directing, and/or requiring one or more of customers, purchasers, and users of the Accused Product to make, use, sell, offer to sell, or import the Accused Product's stock solution with a biological sample suspected of containing a pathogen, either literally or under the doctrine of equivalents, knowing that such acts if taken would infringe the '256 Patent.

278. Spectrum knew or was willfully blind to the fact that it was contributing to and inducing infringement by others, including customers, purchasers, and users, who were practicing one or more claims of the '256 Patent.

279. Spectrum knowingly and actively aided and abetted the direct infringement of the '256 Patent by instructing and encouraging its customers, purchasers, and users to purchase and use the Accused Product as intended, knowing that such actions if taken would infringe. Such instructions and encouragement included, but are not limited to, advising third parties to purchase and use the Accused Product in an infringing manner, providing a mechanism through which third parties may infringe the '256 Patent, and by advertising and promoting the use of the Accused Products in an infringing manner, and distributing guidelines and instructions to third parties on how to purchase and use the Accused Product in an infringing manner.

280. Spectrum's indirect infringement is willful, wanton, and deliberate, permitting increased damages under 35 U.S.C. § 284 and attorneys' fees and costs incurred under 35 U.S.C. § 285.

281. Spectrum's indirect infringement of the '256 Patent has injured and continues to injure Longhorn in an amount to be proven at trial, but not less than a reasonable royalty.

JURY DEMAND

Plaintiffs demand a jury trial on all issues triable by right of jury.

PRAYER FOR RELIEF

Wherefore, Longhorn prays for judgment as follows.

- A. To enter judgment that Spectrum has infringed and is infringing the Asserted Patents;
- B. To enter an order temporarily and permanently enjoining Spectrum and its officers, agents, servants, employees, attorneys, and all persons in active concert or participation with any of them, from infringing the Asserted Patents, and from manufacturing, selling, or offering for sale the Accused Product, and for all further and proper injunctive relief pursuant to 35 U.S.C. § 283;
- C. To award Longhorn damages in amounts sufficient to compensate it for Spectrum's infringement of the Asserted Patents, together with prejudgment and post judgment interest and costs, pursuant to 35 U.S.C. § 284;
- D. To increase the damages awarded Longhorn by reason of Spectrum's willful, wanton, and deliberate infringement of the Asserted Patents;

- E. To declare this case exceptional under 35 U.S.C. § 285 and to award Longhorn its attorneys' fees, expenses, and costs incurred in this action;
- F. An accounting of all of Spectrum's infringing sales and revenues; and
- G. To award Longhorn such other and further relief as this Court deems just and proper.

DATED: January 8, 2021

STOEL RIVES LLP

/s/ Kenneth B. Black

Kenneth B. Black

Attorneys for Plaintiff

Longhorn Vaccines & Diagnostics, LLC